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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,697	10/17/2003	Igor Lifshitz	1662/61606	4669
26646	7590	10/13/2005		EXAMINER
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004				SHIAO, REI TSANG
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/688,697	LIFSHITZ ET AL.
	Examiner	Art Unit
	Robert Shiao	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on responses filed on 08/11/2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-23, 25 and 26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/13/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Claims 1-26 are pending in the application.

Responses to Election/Restriction

2. Applicant's election without traverse of Group III claim 24 in the reply filed on August 11, 2005, is acknowledged. Claims 1-23 and 25-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Breen et al. US 5,859,258.

The instant claim is drawn to a product-by-process claim, which is a compound losartan potassium powder or crystal powder of losartan potassium, and the instant compound is found on pages 4-12 of the specification.

Breen et al. disclose a compound crystal losartan potassium powder, i.e., crystal losartan potassium is milled or blended, see column 4, lines 35-62, and columns 8-10.

Breen et al. compound clearly anticipate the instant claimed compound. It is noted that the preamble, i.e., characteristics or processes of making of instant claimed compound, does not obtain any patentability weight, see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Breen et al. US 5,859,258 in view of Cheronis's publication "Semimicro Experimental Organic Chemistry", 1958, Chapter 5, or in view of Brittain's publication, Polymorphism in Pharmaceuticla Solids, 1999, pages 334-338.

Applicants claim a compound losartan potassium powder or crystal powder of losartan potassium, and the instant compound is found on pages 4-12 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Breen et al. disclose a compound crystal losartan potassium powder, i.e., crystal losartan potassium is milled or blended, see column 4, lines 35-62, and columns 8-10.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant crystal losartan potassium powder compound and Breen et al. is that Breen et al. silence the instant Hausner ratio of the claimed compound. It is noted that the preamble, i.e., characteristics or processes of making of instant claimed compound, does not obtain any patentability weight, see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

Cheronis disclose a process using various conditions (i.e., solvent or temperature) of preparing crystalline form of compounds.

Brittain teaches a process of reducing the particle size of a crystalline compound by milling in an effort to improve formulation homogeneity or dissolution and bioavailability.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claim 24 prima facie obvious because one would be motivated to employ the milled crystal compounds of Breen et al., Cheronis's teachings, and Brittain's teachings to obtain instant crystal powder of losartan potassium, wherein the crystal losartan potassium is milled as powder.

The skill of crystallization and/or milling as powder in choosing proper solvent, temperature and concentration so that crystals form is empirical skill well taught and recognized conventionally in the chemical art, see Cheronis's Laboratory manual,

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chapter 5, and Brittain's publication. The employment of a conventional obvious modification for a known compounds and process to obtain an instant pure crystalline form as powder is considered *prima facie* obvious in the absence of unexpected results.

To demonstrate unobviousness, applicants must show unexpected result stemming from the instant crystalline form over the crystalline form of Breen et al., in form of mechanical advantage(s) of the instant crystal over the crystal of Breen et al., see *Ex parte Conn and Norman*, 119 USPQ 388 (1956), also see *In re Grose & Flanigen*, 201 USPQ57.

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of crystals to secure a pure and stable product. There is no patentable distinction in the concept of a chemical compound in crystalline form or its powder over the same compound, i.e., Breen et al. compounds, see *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic (i.e., powder) of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 24 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21,37, 44 and 53 of Dolitzky et al. co-pending application No. 10/293,820, see US 2004/0006237 A1, in view of Cheronis's publication "Semimicro Experimental Organic Chemistry", 1958, Chapter 5, or in view of Brittain's publication, Polymorphism in Pharmaceutical Solids, 1999, pages 334-338. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound losartan potassium powder or crystal powder of losartan potassium, and the instant compound is found on pages 4-12 of the specification.

Dolitzky et al. claim a crystalline losartan potassium, i.e. Form IV or V.

The difference between instant crystal losartan potassium powder compound and Dolitzky et al. is that Breen et al. silence the instant Hausner ratio of the claimed compound.

Cheronis disclose a process using various conditions (i.e., solvent or temperature) of preparing crystalline form of compounds.

Brittain teaches a process of reducing the particle size of a crystalline compound by milling in an effort to improve formulation homogeneity or dissolution and bioavailability.

One having ordinary skill in the art would find the claim 24 prima facie obvious because one would be motivated to employ the crystal compounds of B Dolitzky et al., Cheronis's teachings, and Brittain's teachings to obtain instant crystal powder of losartan potassium, wherein the crystal losartan potassium is milled as powder.

The skill of crystallization and/or milling as powder in choosing proper solvent, temperature and concentration so that crystals form is empirical skill well taught and recognized conventionally in the chemical art, see Cheronis's Laboratory manual, chapter 5, and Brittain's publication. The employment of a conventional obvious modification for a known compounds and process to obtain an instant pure crystalline form as powder is considered prima facie obvious in the absence of unexpected results.

To demonstrate unobviousness, applicants must show unexpected result stemming from the instant crystalline form over the crystalline form of Dolitzky et

al. in form of mechanical advantage(s) of the instant crystal over the crystal of Dolitzky et al., see *Ex parte Conn and Norman*, 119 USPQ 388 (1956), also see *In re Grose & Flanigen*, 201 USPQ57.

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of crystals to secure a pure and stable product. There is no patentable distinction in the concept of a chemical compound in crystalline form over the same compound, i.e., Breen et al. compounds, see *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic (i.e., powder) of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

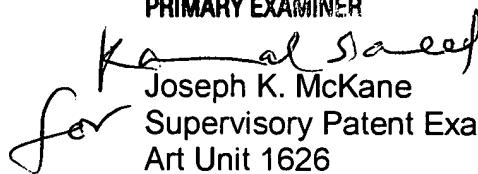
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone

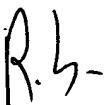
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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 30, 2005